IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9173

Bartle, J. December 5, 2013

Pamela C. Tyler ("Ms. Tyler" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Duncan Salmon, M.D., F.A.C.C. Based on an echocardiogram report dated April 14, 2000,[3] Dr. Salmon attested in Part II of claimant's Green Form that Ms. Tyler suffered from moderate mitral

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. The attesting physician relied on the report of claimant's echocardiogram because claimant was unable to obtain a copy of the echocardiogram tape. See Settlement Agreement § VI.C.2.f. The Trust did not contest that claimant had submitted the affidavit required to rely on an echocardiogram no longer in existence.

regurgitation, mitral valve prolapse,[4] mitral annular calcification,[5] and an abnormal left atrial dimension.[6] Based on such findings, claimant would be entitled to Matrix B-1, Level II benefits in the amount of $108,673.[7]

In the report of claimant's April 14, 2000 echocardiogram, the reviewing cardiologist, Rodney A. Johnson, M.D., F.A.C.C., stated that claimant had "moderate mitral insufficiency." Dr. Johnson, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20%

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4. The presence of mitral valve prolapse requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve. See Settlement Agreement § IV.B.2.d.(2)(c)ii)b).

5. The presence of mitral annular calcification also requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d).

6. Dr. Salmon also attested that claimant suffered from moderate aortic regurgitation, mitral annular calcification, and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

7. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Trust disputes that claimant had an abnormal left atrial dimension, which is one of the complicating factors necessary for a Level II claim, we need not resolve this issue given our determination with respect to claimant's level of mitral regurgitation.

of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In November, 2008, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala determined that there was no reasonable medical basis for Dr. Salmon's representation that Ms. Tyler had moderate mitral regurgitation. Dr. Penkala explained:

> To me the [mitral regurgitation] appears to be trivial on the study dated 12/13/00 and mild on the study dated 12/12/02. I think it is very unlikely that the [mitral regurgitation] was truly moderate on the [echocardiogram] study dated 4/14/00 (tape not available).

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Tyler's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, Ms. Tyler argued that the Settlement Agreement permits a claimant to seek Matrix Benefits based solely on an echocardiogram report where, as Ms. Tyler has done, a claimant submits the necessary affidavit that an echocardiogram is no longer in existence. Claimant further

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Tyler's claim.

asserted that the Trust violated the Settlement Agreement by improperly denying her claim based on the auditing cardiologist's review of her December 13, 2000 and December 12, 2002 echocardiograms.[9] Claimant also submitted a videotaped statement under oath of Dr. Salmon, wherein he explained how he concluded that claimant had moderate mitral regurgitation.[10] Finally, claimant submitted an affidavit of Dr. Salmon, wherein he stated, that:

> I have authored a Green Form in the claim of Pamela Tyler. It is my conclusion, to a reasonable degree of medical certainty, that the April 14, 2000 echocardiogram demonstrates conditions which entitle the Claimant, Ms. Tyler, to Matrix Benefits from the AHP Nationwide Settlement.
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> The basis for the qualifications for Matrix Benefits in this specific claim is based upon Ms. Tyler having moderate mitral regurgitation concomitant with a left atrium measurement of 4.1 [cm]. It is also pertinent to note that she had moderate

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9. Although claimant argued "no effort was made by the Trust or auditing cardiologist to review other echocardiograms by the first reviewing cardiologist, Rodney Johnson, M.D.," she did not identify any other echocardiograms of Dr. Johnson that should have been reviewed. Ms. Tyler also asserted that the echocardiograms used to support the denial of her claim were "based upon a review, on third generation videotape, most likely 7-10 years old. Further, the revolving [echocardiogram] review is based upon different echocardiogram machines." The auditing cardiologist and the Technical Advisor, however, were able to review claimant's echocardiograms without any difficulty.

10. Claimant also submitted a June 17, 2003 letter from Evan Selsky, M.D., F.A.C.C. Although claimant asserts this letter may assist in explaining the change in her level of mitral regurgitation from April 14, 2000 until her later echocardiograms, Dr. Selsky only discusses claimant's aortic insufficiency, which is not at issue in this claim.

aortic regurgitation. Ms. Tyler's claim is reduced in value based upon the confounding finding of mitral valve prolapse, and thus, should be placed on Matrix B, Level II.

I have not reviewed the actual videotape of this echocardiogram. I am aware that the videotape is irretrievably lost. My conclusions are based upon the echocardiography report of April 14, 2000 signed by Rodney A. Johnson, M.D. I personally know Dr. Johnson. I am aware of his qualifications and am proud to call him a colleague. I have reviewed other echocardiogram reports and their videotapes that were authored by Dr. Johnson and have concurred with the findings of Dr. Johnson in said echocardiograms.

I am aware that the AHP Settlement requires using the Singh Criteria in determining Matrix Benefits. It is my experience that the Singh Criteria regarding mitral regurgitation is different than what was typically used to determine moderate mitral regurgitation in my general locality. In other words, the ratio used in the Singh Criteria for mitral regurgitation of a moderate degree, typically required less regurgitation for a moderate finding than what was used on a common basis prior to the AHP Settlement.

Reviewing a report from another physician and accepting its conclusions are a common occurrence in my everyday practice. In treating my patients, I am required daily to accept the findings of other competent physicians in tests such as echocardiograms, blood tests and other similar diagnostic measures. It is an accepted part of my practice to rely upon tests and/or studies performed by other physicians and/or entities. Relying upon the findings of Rodney A. Johnson, M.D. in this matter is not a difficult task. Based upon my knowledge of Dr. Johnson's expertise, I am confident within a reasonable degree of medical certainty that Ms. Tyler qualifies for Matrix

> Benefits from the AHP Settlement as related above.[11]

Thus, according to claimant, "[t]he [t]otality of [c]ircumstances" supports the payment of her claim.[12]

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Penkala submitted a declaration, in which she again concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. In her declaration, Dr. Penkala stated, in relevant part, that:

> 11. At Audit, I found that the 12/13/00 echocardiogram demonstrated trivial (trace) mitral regurgitation. At Contest, reviewed the 12/13/00 study in its entirety and frame-by-by-frame [sic]. I also reviewed the study at those points identified by Dr. Salmon as demonstrating moderate mitral regurgitation. I disagree with Dr. Salmon's assessment that the mitral regurgitation seen on this study is moderate. Several of the frames that purportedly show[] blue color that 'almost fills the [left atrium]' appear to be taken in early systole, and do not depict true mitral regurgitation. I agree with Dr. Salmon that the mitral

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11. Claimant also argues that, together with Dr. Salmon, "four cardiologists disagree with Dr. Penkala's finding."

12. In contest, claimant also submitted a number of other materials related to the Trust's audits of Matrix claims, which according to claimant, "raise concerns as to the auditing process and echocardiogram reader variability." We disagree. Claimant makes no attempt to explain how these materials had any impact on Dr. Penkala's review of her specific claim. As we consistently have stated, the relevant inquiry is whether a claimant has established a reasonable medical basis for his or her claim, an inquiry that is to be made on a claim-by-claim basis. See, e.g., Mem. in Supp. of PTO No. 6280, at 9 (May 19, 2006).

> regurgitation present on this study is eccentric and is better appreciated in the parasternal long axis view, however the mitral regurgitation appreciated in the parasternal long axis view is, at most, mild. In the apical four-chamber view, I found only a small jet of true mitral regurgitation, which was trace/trivial.
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> 14. .... I reexamined the study at Contest, and I confirm my findings that mitral regurgitation is mild .... I agree with Dr. Salmon that the jet 'skirts the posterior wall,' as it is definitely an eccentric jet that might be missed in an apical view. Mitral regurgitation appears mild in the parasternal long axis view.
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> ....
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> 17. Dr. Salmon speaks of his reliance upon the interpretation of the 4/14/00 study by Dr. Rodney Johnson, and speaks very highly of Dr. Johnson's accuracy and reliability in [echocardiogram] interpretation based on personal experience. However, the 4/14/00 [echocardiogram] report which describes moderate mitral regurgitation also describes moderate mitral valve prolapse, a condition which is not evident on the 12/13/00 and 12/12/02 studies. That the 4/14/00 study describes mitral valve prolapse (a condition not known to improve over time), which is not evident on either of the available studies, raises concerns about the accuracy and reliability of the findings reported on the 4/14/00 [echocardiogram] report.
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> 18. Based upon my review of the ... available 12/13/00 and 12/12/02 studies, I do not believe that the 4/14/00 echocardiogram of attestation, if available for review, would demonstrate moderate mitral regurgitation ....

> Accordingly, I affirm my findings at audit, that there is no reasonable medical basis for the Attesting Physician's Green Form representations that Claimant's 4/14/00 echocardiogram study demonstrates moderate mitral regurgitation ....[13]

The Trust then issued a final post-audit determination again denying Ms. Tyler's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On August 19, 2009, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8253 (Aug. 19, 2009).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant advised the Special Master she would not file a response, instead, relying on the material she submitted in contest. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[14] to review

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13. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular place or <+ 5% RJA/LAA."

14. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through (continued...)

claims after the Trust and claimant have had their opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed claimant's December 13, 2000 and December 12, 2002 echocardiograms and concluded that there was no reasonable basis

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14. (...continued)
the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

for the attesting physician's findings that claimant had moderate mitral regurgitation. Specifically, as to claimant's December 13, 2000 echocardiogram, Dr. Vigilante explained:

> Visually, only trace mitral regurgitation was suggested in the parasternal long-axis and apical views with a very eccentric jet traveling slightly posteriorly with the left atrium. I digitized the cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet could best be evaluated in the mid portion of systole. I was able to accurately planimeter the mitral regurgitant jet in the mid portion of systole. In the apical four chamber view, the largest representative RJA was 0.9 cm2. The LAA in the apical four chamber view was 18.2 cm2. Therefore, the largest representative RJA/LAA ratio in the apical four chamber view was 5% diagnostic of very mild mitral regurgitation. In the apical four chamber view, the largest representative RJA was 0.9 cm2. The LAA in the apical two chamber view was 16.9 cm2. Therefore, the largest representative RJA/LAA ratio in the apical two chamber view was 5% diagnostic of very mild mitral regurgitation.

As to claimant's December 12, 2002 echocardiogram, Dr. Vigilante observed:

> Visually, mild mitral regurgitation was suggested in the apical views. This regurgitant jet was a posteriorly directed jet into the left atrium. I digitized the cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet could best be evaluated. In the apical four chamber view, the largest representative RJA was 1.9 cm2. The LAA in the apical four chamber view was 18.2 cm2. Therefore, the largest representative RJA/LAA ratio was 10% qualifying for mild mitral regurgitation. In the apical two chamber view, the mitral regurgitant jet was within 1 cm of the mitral annulus classic for trace mitral regurgitation.

Based on his review of claimant's echocardiograms, Dr. Vigilante concluded that:

> ... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, neither [of] the reviewed echocardiographic studies came close to demonstrating moderate mitral regurgitation with comments as above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on these studies even taking into account the issue of inter-reader variability. It is also unlikely that the April 14, 2000 echocardiogram would have demonstrated moderate mitral regurgitation.[15]

After reviewing the entire show cause record, we find claimant's arguments are without merit. As an initial matter, claimant does not refute the specific conclusions of the auditing cardiologist or the Technical Advisor that her December 13, 2000 echocardiogram and her December 12, 2002 echocardiogram reveal neither moderate mitral regurgitation nor an abnormal left atrial dimension.[16] In particular, the auditing cardiologist determined

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15. Despite an opportunity to do so, claimant did not submit a substantive response to the Technical Advisor Report. See Audit Rule 34. Instead, she requested another review of her claim because the Special Master "previously had decided that Gary J. Vigilante, M.D. would not be an Auditing Cardiologist in claims where Dr. Mark Applefeld was the Attesting Cardiologist." Dr. Applefeld was not the attesting physician or, it appears, even involved, in Ms. Tyler's claim. Thus, we need not address this issue. See Mem. in Supp. of PTO No. 8510, at 10 n.11 (July 29, 2010).

16. The report for claimant's December 12, 2002 echocardiogram specifically states that claimant has only mild mitral regurgitation. Further, the videotaped testimony of the attesting physician taken by claimant's counsel also is not definitive. Dr. Salmon states that the level of claimant's

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that claimant's December 13, 2000 echocardiogram demonstrated only trivial mitral regurgitation and her December 12, 2002 echocardiogram demonstrated mild mitral regurgitation. Similarly, the Technical Advisor concluded that claimant's December 13, 2000 echocardiogram demonstrated "very mild mitral regurgitation" and her December 12, 2002 echocardiogram demonstrated mild mitral regurgitation.

Instead, claimant argues that the Trust could not rely on Ms. Tyler's later echocardiograms in determining whether there was a reasonable medical basis for the attesting physician's representation of moderate mitral regurgitation. In support of this argument, claimant relies on § VI.C.1.c. of the Settlement Agreement:

> A Diet Drug Recipient who demonstrates to the Trustees and/or Claims Administrator(s) that he or she had an Echocardiogram conducted between September 30, 1999, and the date of commencement of Class Notice which a Qualified Physician reported as showing that he or she had FDA Positive regurgitation shall not be disqualified from receiving settlement benefits if the Echocardiogram does not meet all of the requirements of Section VI.C.1.b. above.[17]

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16. (...continued)
mitral regurgitation on her December 13, 2000 echocardiogram is "at least mild" and "possibly moderate in some views." Thus, claimant's assertion that four cardiologists disagree with the auditing cardiologist as to the level of claimant's mitral regurgitation is inaccurate.

17. Section IV.C.1.b. of the Settlement Agreement sets forth certain requirement regarding echocardiograms performed after September 30, 1999.

Contrary to claimant's argument, nothing in this provision requires the payment of Ms. Tyler's claim for Matrix Benefits. The claimant is correct in noting that the Settlement Agreement, upon the satisfaction of certain conditions, allows a claimant to rely on the results of an echocardiogram when the echocardiogram itself can no longer be located. See Settlement Agreement §§ VI.C.2.e. and f. However, nothing in the Settlement Agreement requires the Trust simply to accept the findings stated in an echocardiogram report where the echocardiogram tape is no longer in existence.

Further, claimant's argument ignores § VI.E.6. of the Settlement Agreement, which states:

> In conducting an audit of those Claims and Requests for Credit selected for audit, the Trustees and/or Claims Administrator(s) shall follow the following procedure: All Accelerated Implementation Option acceptance form(s) ("PINK FORM"), registration form(s) ("BLUE FORM"), videotapes or disks of Echocardiograms, medical reports, and other information submitted by AHP in support of a Request for Credit or by a Class Member in support of a Claim, together with a copy of the claimant's medical records, and Echocardiogram videotapes or disks obtained by the Trustees/Claims Administrator(s) shall be forwarded to a highly-qualified, independent, Board-Certified Cardiologist (hereinafter referred to as the "Auditing Cardiologist") selected by the Trustees/ Claims Administrator(s). After thoroughly reviewing these materials, the Auditing Cardiologist shall make a determination as to whether or not there was a reasonable medical basis for the representations made by any physician in support of the Claim or Request for Credit.

Id. § VI.E.6.; see also Audit Rule 7(a). Accepting claimant's interpretation would effectively negate this provision of the Settlement Agreement.

Claimant's interpretation also is not supported by the parties responsible for drafting the Settlement Agreement, namely, Class Counsel and Wyeth. In October, 2010, we requested the views of Wyeth and Class Counsel as to the parties' intention with respect to § VI.C.4.b. and §§ VI.C.2.e. and f. of the Settlement Agreement. See PTO No. 8579 (Oct. 18, 2010). In a joint response, Class Counsel and Wyeth stated their position as follows:

> Where the tape or disk of the Qualifying Echocardiogram, the echocardiogram that supports the presence of a Matrix Level condition and/or the echocardiogram that supports the presence or absence of a Reduction Factor no longer exists or cannot be found, the Class Member must submit a sworn affidavit from the last custodian of the tape or disk documenting that such tape or disk no longer exists and explaining to the satisfaction of the Trust the circumstances under which the tape or disk "came to be misplaced or destroyed."
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> If the Class Member makes that showing, the Trust may rely upon other medical evidence regarding the presence or absence of the regurgitation diagnosed by the Qualifying Echocardiogram, the presence or absence of a Matrix Level condition, and the presence or absence of a Reduction Factor, including the written [echocardiogram] report of the missing tape or disk prepared when the echocardiogram was conducted and all other Medical Information submitted on the claim, such as hospital records, results of cardiac catheterizations, surgical reports, pathology reports, and any other echocardiogram studies. The Auditing Cardiologist shall

> weigh all such Medical Information and the totality of the medical facts presented in evaluating whether there is a reasonable medical basis for the level of regurgitation on the Qualifying Echocardiogram, the presence of a Matrix Level condition and the absence of pertinent reduction factors as asserted by the Attesting Physician in the Green Form submitted by the Class Member in support of the Class Member's Matrix claim.

(emphasis added.)

This is precisely what occurred here. The claimant was permitted to proceed with her claim upon submission of the required documentation to establish that her April 14, 2000 echocardiogram was no longer in existence. The auditing cardiologist and Technical Advisor equally were permitted to consider, among other things, claimant's December 13, 2000 and December 12, 2002 echocardiograms in determining whether there was a reasonable medical basis for the attesting physician's representations. As a review of those materials revealed that the attesting physician's representations lacked a reasonable medical basis, the Trust properly denied claimant's request for Level II Matrix Benefits.

Claimant's reliance on § VI.C.1.d. of the Settlement Agreement is similarly misplaced. This provision of the Settlement Agreement states:

> A claimant who qualifies for a particular Matrix payment, by virtue of a properly interpreted Echocardiogram showing the required levels of regurgitation and/or complicating factors, after exposure to fenfluramine and/or dexfenfluramine, shall not be disqualified from receiving that Matrix payment in the event that a subsequent

> Echocardiogram shows that the required levels of regurgitation and/or complicating factors are no longer present.

Settlement Agreement § VI.C.1.d. Contrary to Ms. Tyler's argument, claimant had not yet "qualifie[d] for a particular Matrix payment." In particular, we disagree with claimant that the echocardiogram report of her April 14, 2000 echocardiogram established a reasonable medical basis for her claim that she was qualified to receive Level II Matrix Benefits under the Settlement Agreement.

Finally, to the extent claimant argues that inter-reader variability accounts for the difference in the opinions of the attesting physician, the Technical Advisor and the auditing cardiologist, such argument is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the opinions of claimant's cardiologists cannot be medically reasonable where the auditing cardiologist and Technical Advisor concluded, and claimant did not adequately dispute, that Ms. Tyler did not have moderate mitral regurgitation.[18] To conclude otherwise would allow a claimant to receive Matrix Benefits when his or her level of mitral regurgitation is below the threshold established by the

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18. For this reason as well, we reject claimant's assertion that her claim should be paid because Dr. Johnson was in the best position to determine Ms. Tyler's level of mitral regurgitation.

Settlement Agreement. This result would render meaningless the standards established in the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Tyler's claim for Matrix Benefits.